PHARMACY SOCIETY OF WISCONSIN Educational Conference

A Legal Briefing

Friday, April 28, 2006

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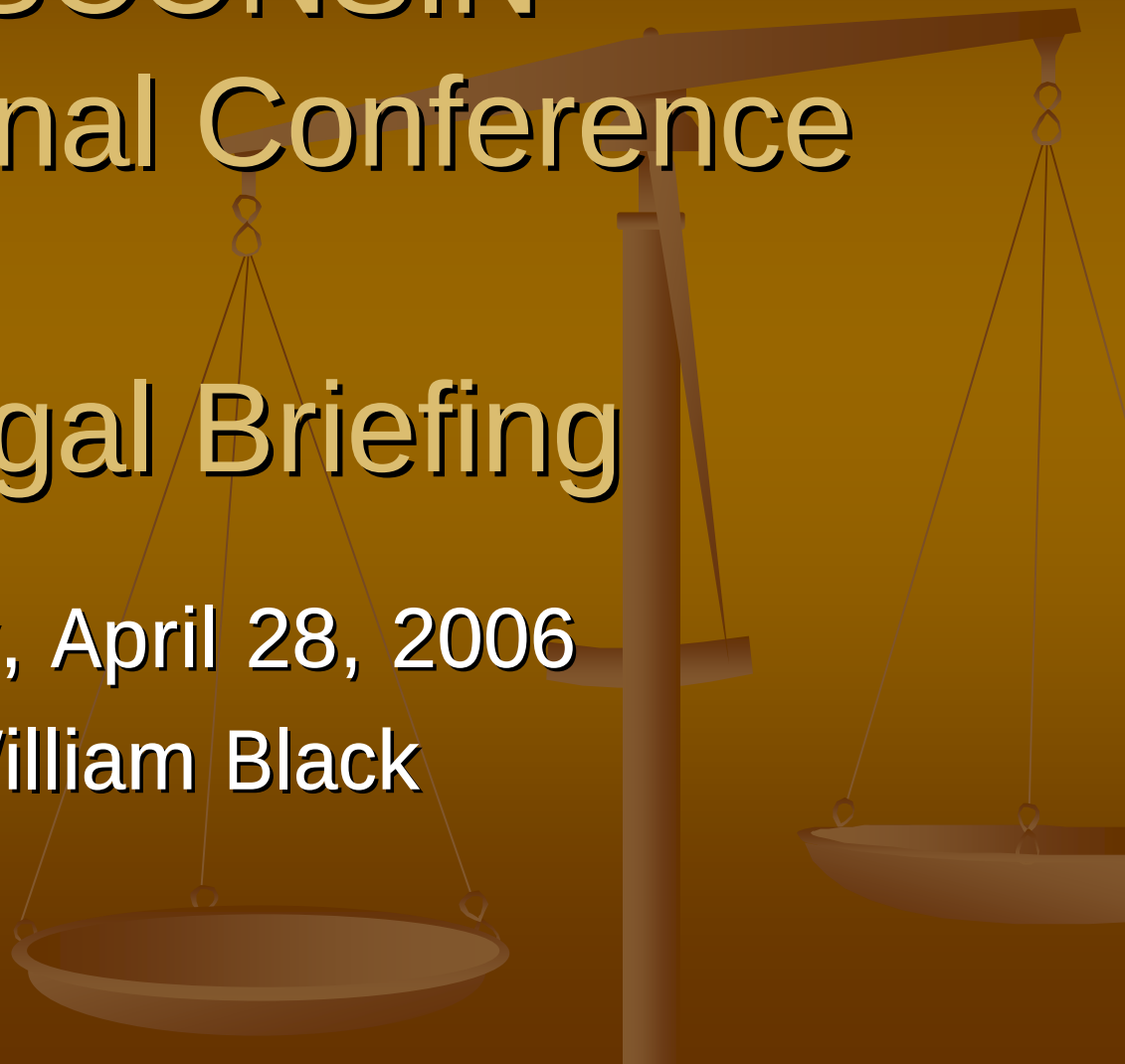
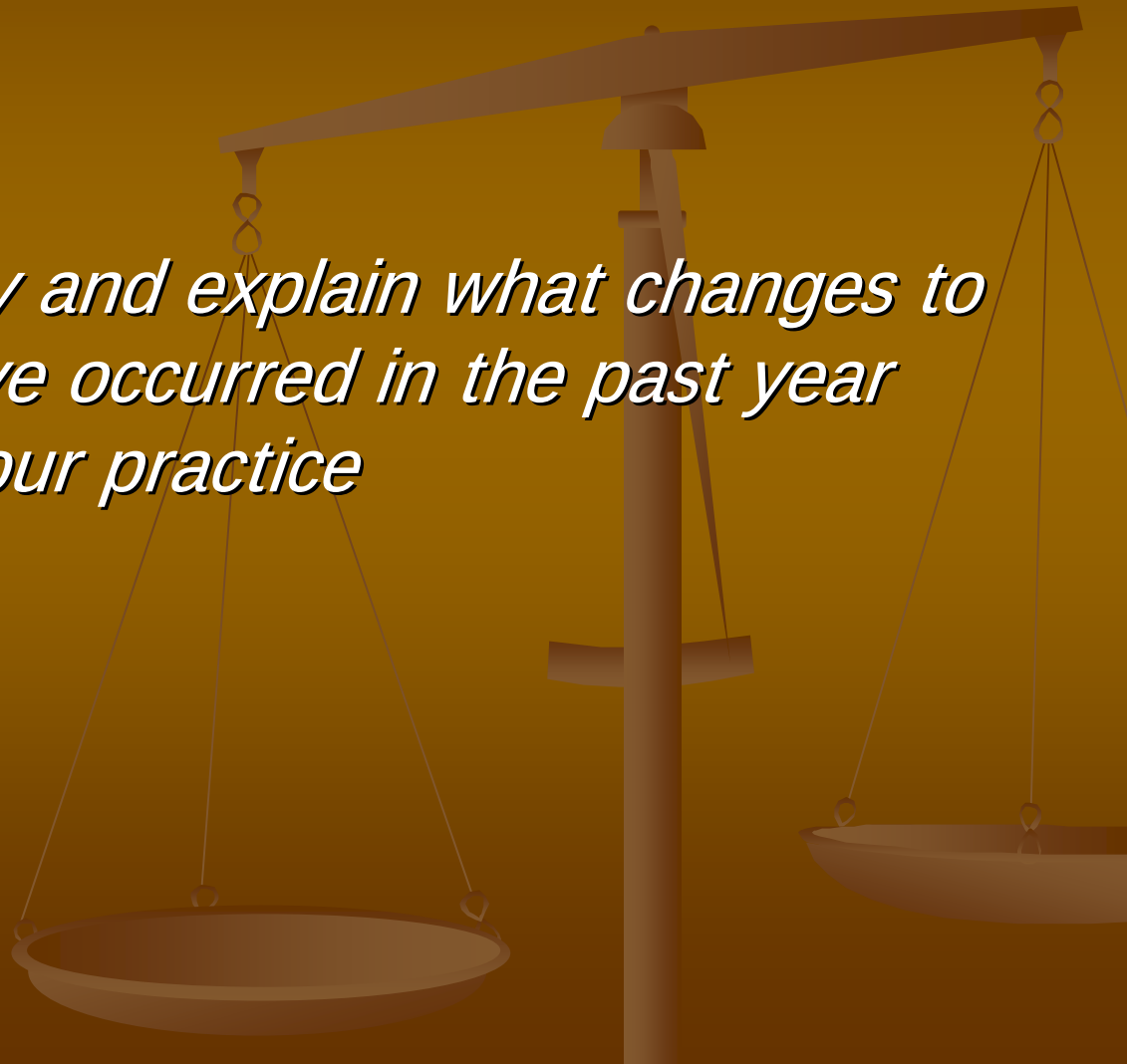


PHARMACY EXAMINING BOARD UPDATE

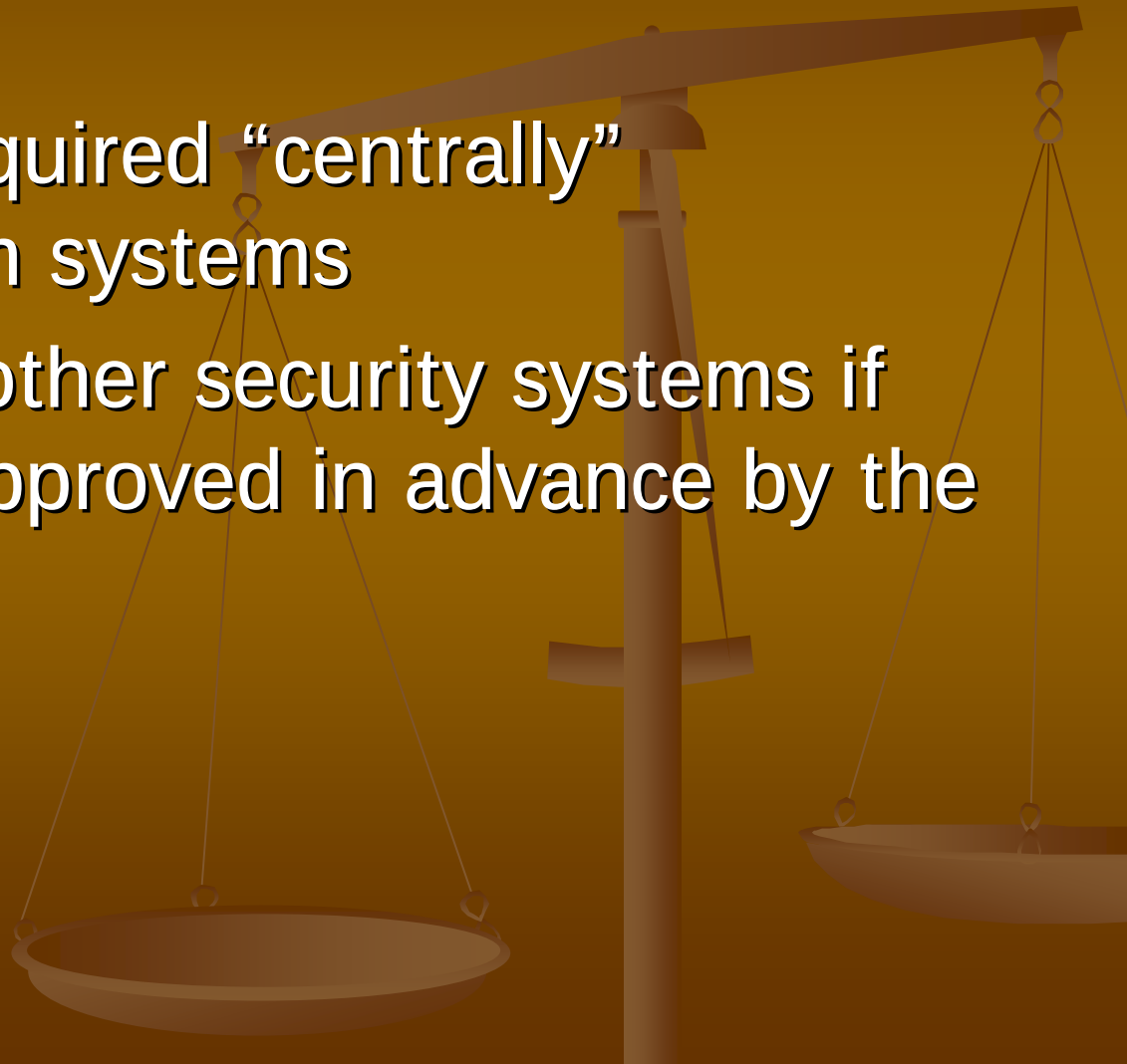


Objective: Identify and explain what changes to pharmacy law have occurred in the past year that will impact your practice

- *State laws*
- *Federal laws*

STATE LAW CHANGES
Administrative Rules

Pharmacy Security Systems



- Previous law required “centrally” monitored alarm systems
- Change allows other security systems if reviewed and approved in advance by the board
- Phar 6.08

RETURN OF HEALTH CARE ITEMS

- Allows the return of health care items from “resident health care patients”
  - Patient residing in a community-based residential facility that controls a resident’s prescribed and over-the-counter medications
  - May only be returned to the pharmacy from which it was dispensed or sold

RETURN OF HEALTH CARE ITEMS

- The health item was never in the possession of the patient
- The health item was dispensed in a tamper-resistant package
- The health item will not be commingled with a different health item
- The health item is in it’s original container and the pharmacist determines the contents are not adulterated or misbranded

RETURN OF HEALTH CARE ITEMS

- Allows returns from “secured institutional health care patients”
  - A jail inmate whose dispensed health care items are maintained under the custody of the jail
  - A juvenile patient who resides in a secured correctional facility, a secured child caring institution, a secured group home, a secured detention facility or a juvenile portion of a county jail

RETURN OF HEALTH CARE ITEMS

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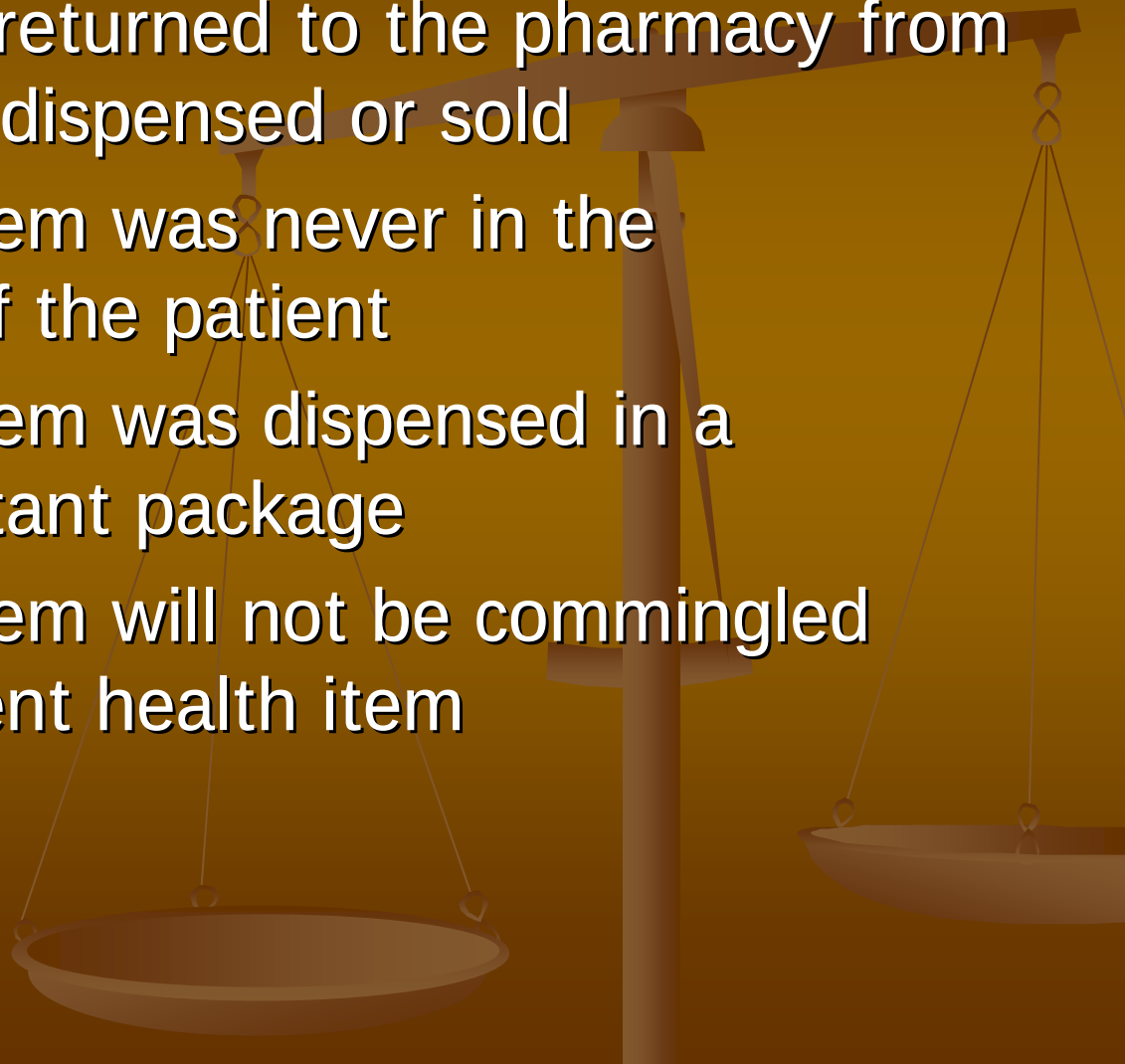


RETURN OF HEALTH CARE ITEMS

- The health item is in it's original container and the pharmacist determines the contents are not adulterated or misbranded
- Items returned must be segregated and may not be re-dispensed or resold other than to a secured institutional health care patient
- Phar 7.04

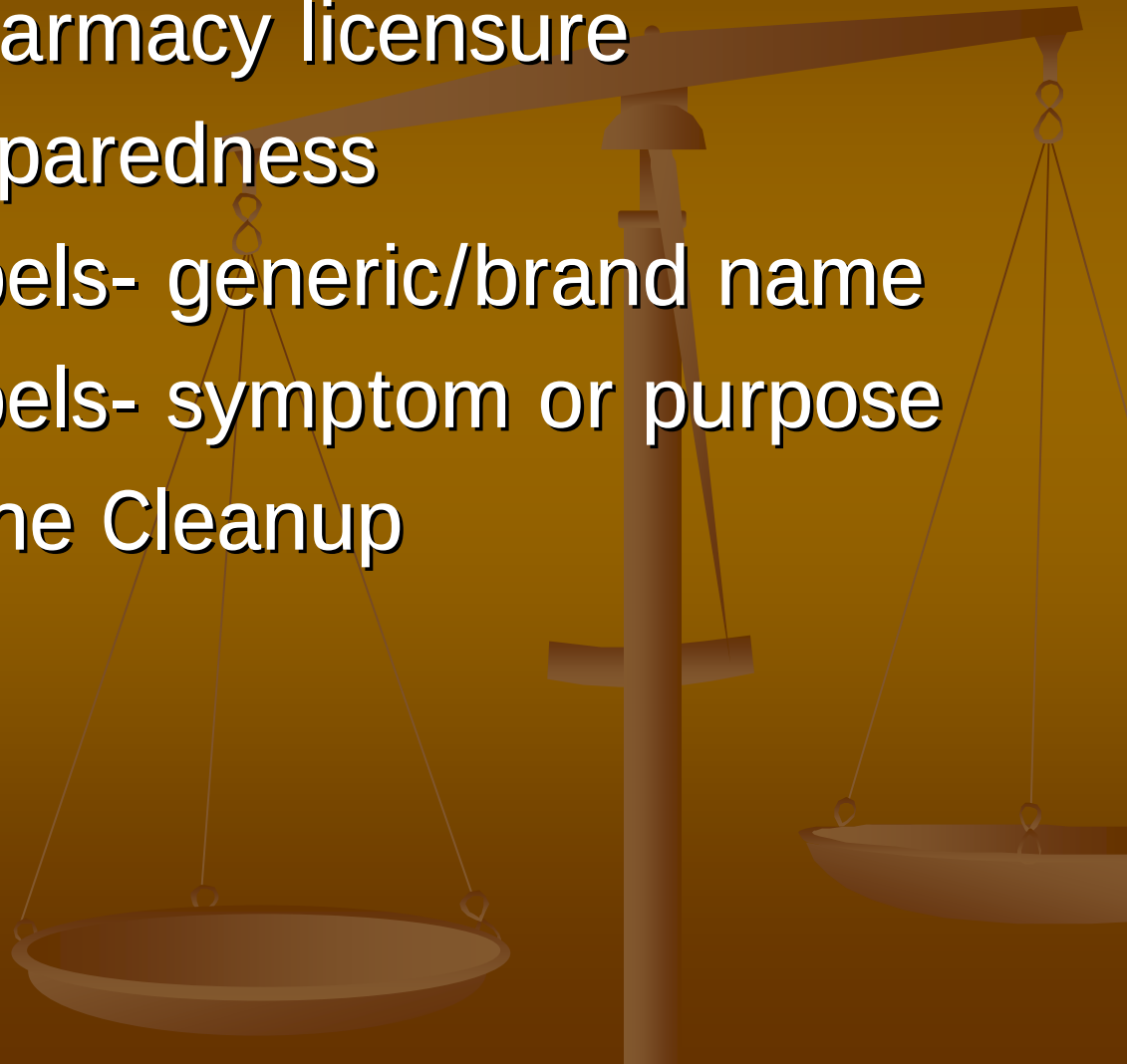
Prescription Order Transfers

- Phar 7.05 revised
  - General record requirements
  - General computer system requirements

- Phar 7.055 created
  - Separates explicit requirements for
    - Computer vs. Verbal (no fax machines allowed unless verbal verification occurs)
    - Controlled vs. Non Controlled (Following Wisconsin law should be consistent with federal law)
    - No longer required- Board review and approval of a real-time common central processing unit.

Wisconsin Statutory Changes

- Out of state pharmacy licensure
- Emergency preparedness
- Prescription labels- generic/brand name
- Prescription labels- symptom or purpose
- Pseudoephedrine Cleanup



Out of State Pharmacy Licensure

- 2005 Wisconsin Act 242- eff. 4/13/2006
- No pharmacy that is in another state may ship, mail, or otherwise deliver a prescribed drug or device to persons in Wisconsin unless the pharmacy is licensed in Wisconsin.
- Allows central fill operations with border state pharmacies without the need for variances.
- Will provide a basic framework for future remote dispensing business models in concert with in-state pharmacies and practitioners. Recognizes the need for regulatory control over patient health care systems that transcend state borders.
- Incremental enforcement effect on legitimate internet pharmacy sales of pseudoephedrine products.

Emergency Preparedness

- 2005 Wisconsin Act 270- eff. 4/20/06

- The board may provide a variance to any pharmacy statute or rule if:
  - A natural or man-made emergency exists (as determined by the board or a designee)
  - A pharmacist requests the variance
  - The variance is necessary to protect the public health
- Valid for 90 days and may be extended upon request.
- The board now has full authority to take steps necessary to-
  - Provide temporary relocation
  - Assist with drug stockpile programs
  - Increase availability of drug administration options
  - Modify labeling, transport, recordkeeping and storage requirements

Prescription labels- generic/brand name

- 2005 Wisconsin Act 195- eff. 4/8/06
- IF a prescription order- specifies a brand name
- AND a pharmacist dispenses the drug product equivalent
- The pharmacist MAY include the brand name on the label as well as the generic name of the drug product equivalent (Unless the practitioner directs otherwise)
- Phar 7.02 impact
  - Implicit repeal- Brand specified->Substituted generic dispensed
  - No implicit repeal- If the order denotes the generic name- Phar 7.02 still applies- No listing of the brand name if that is not the product dispensed.

Prescription labels- symptom or purpose

- 2005 Wisconsin Act 196- eff. 4/8/06
- A patient must indicate IN WRITING to a practitioner that the patient wants the “symptom or purpose” for the prescription to be disclosed on the Rx label.
- The practitioner SHALL specify the symptom or purpose in the prescription order.
- In that instance, the pharmacist SHALL place the symptom or purpose for which the drug is prescribed on the container label.

Pseudoephedrine

- 2005 Wisconsin Act 262- eff. 4/20/06
  - Clean up legislation
  - Clarifies:
    - 7.5 grams means, “7.5 grams of pseudoephedrine contained in a pseudoephedrine product”
    - Access to records (WHO CAN SEE THE LOG)
      - A pharmacist SHALL make the records available to a “law enforcement officer” (undefined) who “requests” them.
        - The log is NO LONGER a patient health care record
        - No court order is needed for a law enforcement officer to review the log
    -

Current WISCONSIN Pseudoephedrine Law (recap)

- Pseudoephedrine and ephedrine are drugs needed for the manufacture of clandestine methamphetamine
- Ephedrine has been a scheduled IV for some time
- Legislation was designed to limit the access to pseudoephedrine
- Needed to also assure access for legitimate use as a medication

Pseudoephedrine Legislation

- Other states around the country were passing legislation to restrict pseudoephedrine sales.
- The number of clandestine meth labs has been increasing every year
- There is now competing federal legislation to restrict the sale of pseudoephedrine and other products.

Pseudoephedrine Legislation

- Restricted sales applies to all single ingredient pseudoephedrine and any combination products containing pseudoephedrine
- It makes these products schedule V drugs
- Liquid and gel cap pseudoephedrine products are not included
- Sale of restricted items is limited to pharmacies (as interpreted)

Pseudoephedrine Legislation

- Sale must be by a pharmacist or someone under the direct supervision of a pharmacist
- The purchaser must show a photo ID
- The purchaser must sign a log book
  - Seller shall record the name and address of the purchaser
  - Seller shall record the name and the quantity of the product sold
  - The purchaser and the selling pharmacist must sign the log

Pseudoephedrine Legislation

- The purchaser must at least 18 years of age
- Purchases are limited to 7.5Gms in 30 days no matter where purchased
- Possession of more than 9 Gms is considered possession with intent to manufacture meth
- The Controlled Substance Board may schedule any other product that it finds can be used to manufacture methamphetamine
- Logs are able to be accessed by law enforcement officers, without a court order

FEDERAL LEGISLATION

- Public Law 109-177

Federal Law- the Basics

- Public Law 109-177
  - Sales limit, purchase limit, packaging requirements, mail order restrictions ALL EFFECTIVE NOW
  - All other provisions- eff. 9/30/06
  - PRODUCTS- (LISTED SUBSTANCES)
    - Pseudoephedrine
    - Ephedrine
    - Phenylpropanolamine

Federal Basics Continued

- Only effects NON Rx. (All references to BASE product)
- Sales limit- 3.6 gm per day
- 9 gm in 30 days
- Blister pack or unit dose (for all non liquids)
- Mail order and Mobile vendor- 7.5 gm in 30 days

- WHAT?- ALL- tablets, gel caps and liquids

MORE Federal Basics Cont'd

- WHERE?- "behind the counter"- Intent is to restrict 'direct' public access. A locked cabinet is ok.
  - The product must be delivered directly into the custody of the purchaser.
- WHO?- You; if you continue to sell-
  - "Regulated seller"- includes pharmacies, grocery stores, mail order, mobile venders

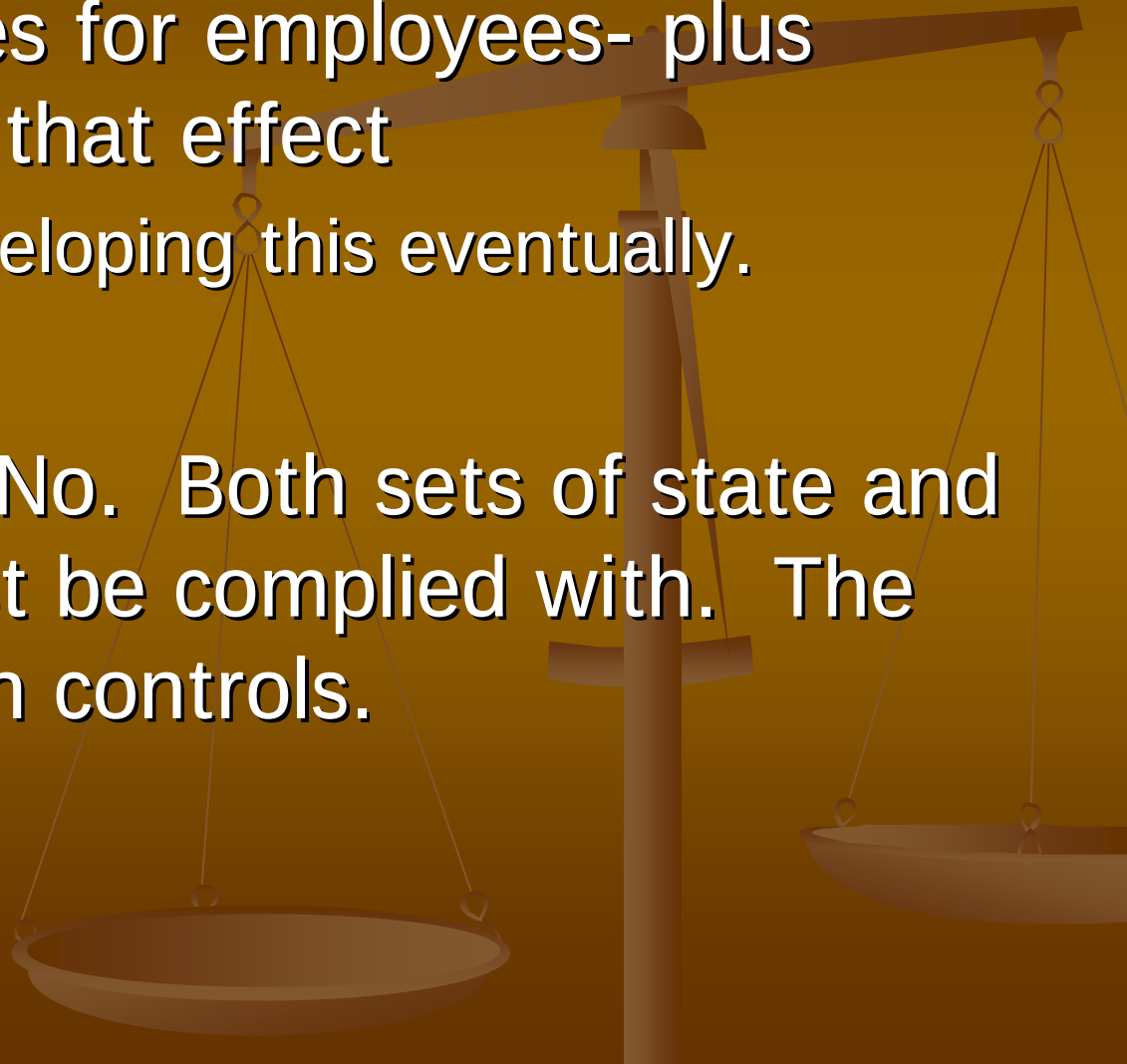
Logbooks

- LOGBOOKS
  - Written or electronic
  - Requirements- proper ID State or Federal, SELLER enters the name of drug and quantity AND the PURCHASER writes=> name and address of purchaser, date, time of sale, and signs
  - Seller verifies that all this matches up
  - NOT NEEDED for 60 mg or less of pseudo only if in a single sales package*****
  - Must contain a “misrepresentation” warning.
  - Access- The federal AG is going to draft up some rules for this. However, Congress has indicated there IS a right to privacy protection which should be reflected in the rules. (Versus Wis.)

And yet more Federal Pseudo

- Training courses for employees- plus certifications to that effect
  - DEA will be developing this eventually.

- PREEMPTION- No. Both sets of state and federal law must be complied with. The stricter provision controls.



“Easy” Compliance Outline to combine federal and state law (Feel free to think up alternatives)

- Where- put it all behind the counter
- What-
  - Pseudo- (solid) 7.5 gm/30 days, 3.6 gm daily limit,
  - (liquid and gel caps) 9 gm/30 days, 3.6 gm daily limit
  - Ephedrine- (ALL FORMS- solid, liquid, gel) 9 gm/30 days, 3.6 gm daily limit
  - Phenylpropanolamine- (ALL FORMS- solid, liquid, gel) 9 gm/30 days, 3.6 gm daily limit

Compliance Cont'd

- Packaging- All must be blister or unit dose except for liquids
- Two Logbooks/One Logbook? (DEA input)-
  - Fed Only: Ephedrine (non Rx, non CIV), Phenylpropanolamine, and Pseudoephedrine liquid and gel caps
    - Never sell more than 3.6 gm/day
    - Never sell more than 9 gm/30 days
    - Don't need to log sales of pseudo if the purchase is a single sales package of not more than 60 mg (liquid or gel cap)
    - These are technically Ch. 146 Health Care Records and not regulated at the state level, therefore no non-fed review without court order.
    - Federal disclosure rule vs. Ch. 146 to be determined. (But DEA can currently view anyway, see; Wis. Stat. 146.82 (2)(a)5.)
  - State and Fed: Pseudo only- Only solids, any amounts
    - Never sell more than 3.6 gm/day
    - Never sell more than 7.5 gm/30 days
    - "Law enforcement officers" can view without court order. (Later DEA rule may restrict this, at least for federal purposes.)

Compliance Cont'd

- Contents of Logbook (morphing requirements for both jurisdictions together- because adding extra requirements is not prohibited by either, but will end up fulfilling both);
  - Require a federal or state ID for verification
  - Seller enters- name of drug and amount
  - Purchaser enters- name, address, date and time of sale
  - Purchaser signs
  - Seller signs (as per current Wisconsin law)
  - Include Federal warning language

On the Horizon

- Theft and loss- “significant loss”
- Internship- Foreign Interns; FPGE cert.
- Remote dispensing- Statutory change vs. rule change
- Drug pedigrees- wholesale distribution requirements; pedigrees, stricter licensing standards.

Electronic Signatures

- 1. Prescription order from practitioner office electronically generated from a computer or handheld device and sent via a modem, or other computer device, ARRIVING at the pharmacy FACSIMILE MACHINE, as a peripheral. = Electronic order. (Electronic signature is required.)

- 2. Prescription order from practitioner office electronically generated from a computer or handheld device and sent via a modem, or other computer device, ARRIVING at the pharmacy COMPUTER. = Electronic order. (Electronic signature is required.)

Electronic Signatures- cont'd

- 3. Written/typed/or computer printed prescription order on hard copy paper placed into a facsimile machine at a practitioner's office and transmitted to the pharmacy which is received at the pharmacy's facsimile machine. = Facsimile order which must meet the requirements of a written prescription order, including a handwritten signature. This type of order must also all meet the requirements of Wis. Admin. Code § Phar 8.12, for faxed prescription orders. Take special note of the restrictions contained in section Phar 8.12 on faxing prescription orders for schedule II controlled substances.

Electronic signatures- cont'd

- 4. Written/typed/or computer printed prescription order on hard copy paper placed into hands of a patient at a practitioner's office which is thereafter presented at the pharmacy. = Written prescription order. Handwritten signature is required.

- 1. The pharmacy may maintain a practitioner signature file for comparison where a computer generated facsimile signature is affixed. By pre-agreement with the pharmacist a practitioner may place a signature on file for comparison.

- 2. The pharmacy may also maintain a code or name file from practitioners wishing to use electronic transmission utilizing a signature that is a printed practitioner name, alpha numeric string or other numbering system for validation, but not constituting public key infrastructure. The signature, in whatever form, cannot be affixed by default, rather the practitioner must perform an affirmative act to affix the signature, contemporaneously with the electronic transmittal of the prescription order.

- 3. Vendors of such systems can assist the acceptance process by educating practitioners to contact a pharmacy prior to using any system in order to obtain agreement regarding, (a) form and content of the order, (b) assuring the pharmacist of the non default application of a signature for the system used, and; (c) any other security measures used with the electronic transmission system. A public key infrastructure (Note, you may see this referred to in technology literature as “PKI”) system could certainly be used by agreement but is not required.

Designation of electronic transmission

- The prescription order must bear the designation, “electronically transmitted prescription”, or with similar words or abbreviations to that effect. Wis. Admin. Code § Phar 7.08 (2)(c) .
- The phrases, “electronically ordered by” or “electronically authorized by”, constitute similar words “to that effect”.

Samples of valid electronic signatures

- If the prescription order is deemed an electronic order, the following types of electronic signatures are permissible (not an all inclusive list) :
- “electronically ordered by Dr. Smith”- If the field, “Dr. Smith” is not a default, rather attached by the practitioner contemporaneously with transmission.
- “electronically authorized by Dr. Smith”- If the field, “Dr. Smith” is not a default, rather attached by the practitioner contemporaneously with transmission.
- “Dr. Smith”- If the field, “Dr. Smith” is not a default, rather attached by the practitioner contemporaneously with transmission.

Samples of valid electronic signatures

- "signed by Dr. Smith"- If the field, "Dr. Smith" is not a default, rather attached by the practitioner contemporaneously with transmission.
- " 1X#aW874, or similar code to which you have direct electronic access or authentic knowledge connecting the code exclusively to a practitioner"- If the field is not a default, rather attached by the practitioner contemporaneously with transmission.
- "Dr. Smith"- If the field is not a default, rather attached by the practitioner contemporaneously with transmission.

DEA impact

- **Controlled Substances - IMPORTANT REMINDER- The DEA does not currently allow the electronic transmission of prescription orders for controlled substances.**
- The DEA considers the electronic transmission of a prescription order for a controlled substance to be an “oral” order. The DEA states that in this instance local state law regarding oral orders will control how the order is handled.